



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Rapid Throughput Standardized Evaluation of Transmissible Risk for Substance Use Disorder in Youth

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on December 3, 2013, page 72682-72683 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute Drug Abuse (NIDA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget,

Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION:

To obtain a copy of the data collection plans and instructions, contact Dr. Augie Diana, Health Scientist Administrator, Prevention Research Branch, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5163, Bethesda, MD 20892, or call non-toll-free number (301) 443-1942 or Email your request, including your address to: dianaa@nida.nih.gov. Formal request for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Rapid Throughput Standardized Evaluation of Transmissible Risk for Substance Use Disorder in Youth, Reference No N44DA-12-5562, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will finalize the development of the Transmissible Liability Index (TLI), thereby advancing the TLI from a research tool to a practical instrument. The TLI is a psychometric tool for detecting youth at elevated risk for substance use disorder (SUD). The TLI, a web-based platform for assessing risk of SUD, is a highly efficient tool both in terms of the limited time

commitment required as well as its low cost. The inexpensive and high efficiency of the TLI for identifying youths in need of prevention, and the strong cost-benefits to society for SUD prevention, portend strong demand for use in a variety of populations including family and social services, schools, mental health facilities, and youth protection agencies. To transform the TLI prototype into a practical instrument, three core tasks remain: (1) Standardization on a sample ($N \sim 5,000$) that is representative of the general population to generate norms that are specific to age, gender and ethnicity; (2) Construct validity analysis using standard parametric modeling techniques to show that heritability accounts for the major portion of variance on TLI scores; the sample (150 identical and 150 fraternal twins) will be representative of the same general population characteristics identified above; and (3) Psychometric analysis of validity and reliability based on the above data. Validating the TLI furthers NIDA's mission by legitimating the tool for exploring the attitudes and social predictors of addictive behaviors with the intention of reducing or eliminating drug-taking behavior. This research is squarely within NIDA's mission of research on drug abuse and addiction, as well as its focus on ensuring the rapid and effective dissemination and use of the results to significantly improve efforts to stem substance use disorder. To move the TLI from the research domain to practical use through commercial dissemination, the research and development team ("the R&D team") needs to satisfy professional quality standards consistent with American Psychological Association regulations. To satisfy those standards, the R&D team must demonstrate the reliability and internal validity of the TLI against existing standardized psychometric studies for youth populations, ages 14 to 18. The 14-to-18 year old age range was selected because it encompasses the years typically spent in high school, which

are known to be the timeframe when substance use is likely to begin and accelerates, often leading to substance abuse disorder. Notably, the peak period for the manifestation of cannabis-use disorder is age 18-19, and the past-year-prevalence for alcohol-use disorder is age 20-22. The TLI is designed to identify the propensity for these and other substance abuse prior to manifestation; as such, collecting data from the high school age group (14-18 years old) is critical to identifying at-risk youths for the purposes of early intervention. Thus, the TLI must be tested with data collected from youth populations, ages 14 to 18, comparable to those in existing studies. Moreover, the R&D team must provide psychometric external validation for the TLI through data collection from sets of identical and fraternal twins. Psychometric analyses are required to show that the TLI performs according to expectations. Accordingly, studies will be performed on the collected information to demonstrate i) construct, ii) discriminative, iii) concurrent, and iv) predictive validity.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,083.

Estimated Annualized Burden Hours

| Type of Respondent: Individuals and Households | Number of Respondents | Responses per Respondent | Average Burden Per Response (in hours) | Annual Hour Burden |
|--|-----------------------|--------------------------|--|--------------------|
| Parent of 14-17 year-old students: Consent Form | 5,000 | 1 | 1/60 | 83 |
| 14-18 year-old students: School Survey (TLI) | | 1 | 30/60 | 2,500 |
| 14-18 year-old youths or their parents: Consent Form | 600 | 1 | 1/60 | 10 |
| 14-18 year-old youths: Twins Survey (Demo/D&A) | | 1 | 10/60 | 100 |
| 14-18 year-old youths: Twins Survey (Dysregulation) | | 1 | 10/60 | 100 |
| 14-18 year-old youths: Twins Survey (TLI) | | 1 | 29/60 | 290 |

Dated: March 19, 2014

Glenda J. Conroy,
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NIDA, NIH.

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